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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,441	08/30/2001	Hai H. Trieu	4002-2643	8143

7590 12/08/2004

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EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,441	TRIEU, HAI H.	
	Examiner	Art Unit	
	Alvin J Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-25 and 48-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8,9,12,13,18,25 and 70* is/are allowed.

6)☒ Claim(s) *3-7,10,11,14-17,19-24,50,53,54,56 and 58-69* is/are rejected.

7)☒ Claim(s) *48,49,51,52,55 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/30/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Claims 3-7, 10, 11, 19-24, 50, 56, 58, 59, 63-66 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin US Patent 5,716,416.

Lin discloses an intervertebral disc comprising a body (see Fig. 1E) having a first end, a central portion, and a second end. The body elastically deforms from a first (see Fig. 1E) to a second configuration (see Fig. 4C). The first configuration has two ends mating with each other and at least one fold.

Regarding claims 5-7, see col. 2, lines 57-60.

Regarding claim 10, every surface has a texture. The texture will depend on the porosity of the material.

Regarding claim 11, every surface has a texture. With regard to claim 11, it is noted that the device of the Lin reference appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claim 19, see attachment.

Regarding claims 20, 21, 23 and 24 see Fig. 1E.

Regarding claim 22, see Fig. 2C.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 15-17, 53, 54, 60-62, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US Patent 5,716,416.

Lin discloses the invention substantially as claimed. However, Lin does not an elastic body made of a polyurethane having at least one growth factor and/or at least one pharmacological agent (e.g. recombinant protein) dispersed in the elastic body.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the Lin reference by changing the material property of the elastic body (e.g. polyurethane) and adding growth factors to the body in order to promote the growth of cell around the implant because Applicant has not disclosed that the material property and the growth factors provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with silicone and hydrogel coatings because both materials promote the growth of tissue and both are biocompatible.

Therefore, it would have been an obvious matter of design choice to modify the Lan reference to obtain the invention as specified in the above claims.

Allowable Subject Matter

Claims 8, 9, 12, 13, 18, 25 and 70 are allowed.

Claims 48, 49, 51, 52, 55, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 09/23/04 have been fully considered but they are not persuasive.

The Examiner approved the changes to the specification clarifying the invention. However, the Applicant's representative didn't make any changes to independent claims 3, 11, 14 and 17 adding new structure limitations defining the center body of the implant. See attachment to observe how the Examiner interpreted the solid center in the 1 st configuration.

In order to overcome the rejection, the Applicant's representative has to clarify (in the claim) where is the solid center of the body. The Applicant has to enter new limitations defining the center body of the implant.

Finally, in addition to the rejection made to claim 11, the last three lines of claim 11 are referring to a product by process claim wherein a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, *489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974)*. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, *333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964)*. In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., *535 F2d 67, 190 U.S.P.Q. 15, see footnote 3 (CCPA 1976)*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart

Alvin J Stewart
Primary Examiner
Art Unit 3738

December 06, 2004.

ATTACHMENT

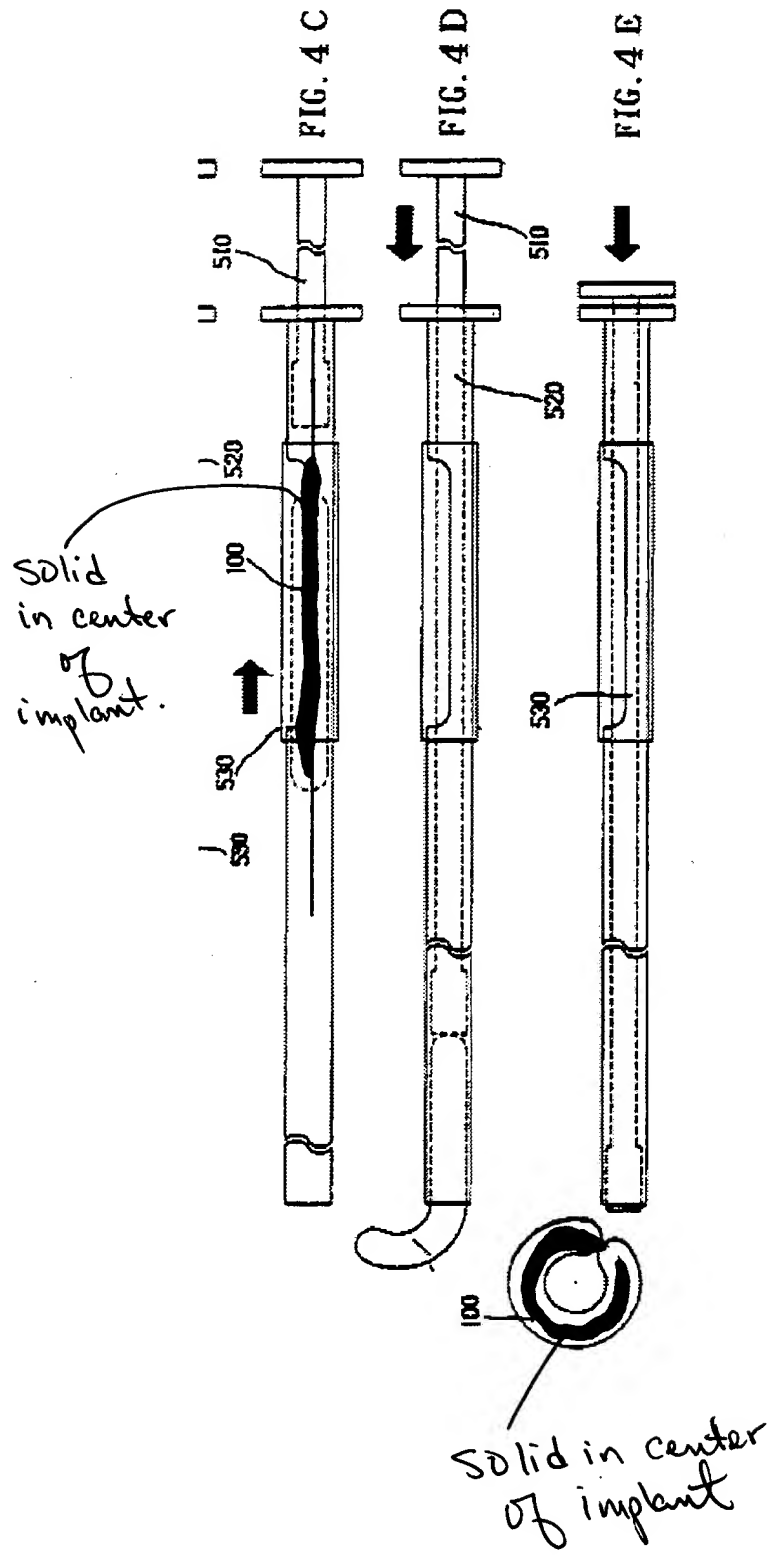
FIG. 4 C
FIG. 4 D
FIG. 4 E
510
520
100
530
500
Solid in center of implant.
Solid in center of implant